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08/619,649	03/27/1996	RADOJE DRMANAC	ARCD:146/BOW	7575

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

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09/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

08/619,649

Applicant(s)

DRMANAC, RADOJE

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97 and 157-176 is/are pending in the application.
- 4a) Of the above claim(s) 176 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 97 and 157-175 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C2)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 8 July 2008 in which claims 97 and 166 were amended. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 8 April 2008 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 97, 157-175 are under prosecution.

Interview Summary

2. Applicant's comments regarding the Interview of 24 April 2008 are noted. During the interview, it was agreed that the description of Fig. 2A as found in the specification does provide support for the physical barrier and hydrophobic surface as claimed. The previous rejection under 35 U.S.C. 112, first paragraph, new matter is withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 97, 157-161, 166-171 are rejected under 35 U.S.C. 102(b) as being anticipated by Brigati (U.S. Patent No. 4,777,020, issued 11 October 1988).

Regarding Claim 97 and 166, Brigati discloses a support (#156) comprising an array of microchips (slides #610, #630) on the support, each of the microchips comprising an array of oligonucleotide probes (#620a-c), each of the microchips being separated by a physical barrier (#622, #642 and space between the slides) and each of the microchips having oligonucleotides of different sequences attached to different locations (i.e. polynucleotides are separated by length via electrophoresis gel and then blotted onto slides, Column 8, lines 1-55 and Fig. 6).

Regarding Claim 157 and 167, Brigati discloses the support provides a space between opposing sides thereby providing a groove along the edge between the slides (Fig. 6).

Regarding Claim 158 and 168, Brigati discloses the support wherein the adjacent slides are separated by silicone shims (Column 4, lines 39-50 and Column 10, lines 30-59).

Regarding Claim 159 and 169, Brigati discloses the support comprising multiple rows and columns (e.g. 30 slide pairs providing 2 rows of 30 columns, Column 7, lines 44-45)

Regarding Claim 160 and 170, Brigati discloses multiple slide pairs arranged in the support to form a gap between the surfaces of the slide pairs for sample application using a pipette (Column 8, lines 37-39). While Brigati teaches use of a pipetting device,

the recitation "for use with a multichannel pipette" is a recitation of intended use which does not further define the invention.

Regarding Claim 161 and 171, Brigati discloses the device wherein the device comprising assay ingredients e.g. labeled sample (Column 10, lines 8-15).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 162 and 172 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brigati (U.S. Patent No. 4,777,020, issued 11 October 1988) in view of Augenlicht (U.S. Patent No. 4,981,783, issued 1 January 1991).

Regarding Claims 162 and 172, Brigati discloses a support (#156) comprising an array of microchips (slides #610, #630) on the support, each of the microchips comprising an array of oligonucleotide probes (#620a-c), each of the microchips being separated by a physical barrier (#622, #642 and space between the slides) and each of the microchips having oligonucleotides of different sequences attached to different locations (i.e. polynucleotides are separated by length via electrophoresis gel and then blotted onto slides, Column 8, lines 1-55 and Fig. 6). Brigati further teaches the nucleic

acids are spotted in defined positions on the slides (Column 10, lines 8-15) but is silent regarding the an 8 x 12 format of spotted probes.

However, spotting probes in an 8 x 12 format was well known and routinely practiced in the art at the time the invention was made as taught by Augenlicht. Augenlicht further teach the format utilizes commercially available spotting pins that are useful for making replica arrays from multiwell cultures and produce precisely defined positions. (Column 6, lines 17-28 and Column 13, lines 55-60). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the 8 by 12 format of Augenlicht to the arrays of Brigati for the expected benefit of providing precisely defined and replicated regions as desired in the art (Augenlicht, Column 13, lines 55-60).

7. Claims 163-165 and 173-175 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brigati (U.S. Patent No. 4,777,020, issued 11 October 1988) in view of Southern et al (Genomics, 1992, 13: 1008-1017).

Regarding Claims 163-165 and 173-175, Brigati discloses a support (#156) comprising an array of microchips (slides #610, #630) on the support, each of the microchips comprising an array of oligonucleotide probes (#620a-c), each of the microchips being separated by a physical barrier (#622, #642 and space between the slides) and each of the microchips having oligonucleotides of different sequences

attached to different locations (i.e. polynucleotides are separated by length via electrophoresis gel and then blotted onto slides, Column 8, lines 1-55 and Fig. 6). Brigati further teaches the nucleic acids are spotted in defined positions on the slides (Column 10, lines 8-15) but is silent regarding the number of spotted probes, the length of spotted probes and the synthesis of the probes.

However, high density arrays having more than 256 probes of 4-9 bases and synthesized on the array were well known in the art at the time the claimed invention was made as taught by Southern.

Southern et al disclose a support comprising an array of arrays, each having an array of oligonucleotide probes immobilized wherein each array is a quadrant on the surface (Fig. 3, figure legend, line 1). Southern et al further teach the support wherein the array of microchips comprises more than 256 probes wherein the probes are between 4 and 9 bases (Fig. 3) and wherein the probes are synthesized on the support (page 1009, left column).

Southern also teach that the high-density arrayed probes provide an automated and powerful tool for comparing related sequences and detecting mutations (Abstract). Brigati is specifically interested in comparative analysis of samples (Column 9, lines 63-Column 10, line 15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the nucleic acid spots of Brigati using the high density and in situ synthesized probes of Southern. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the added benefits of automated analysis using a

substrate known as a powerful tool for comparing related sequences and detecting mutations (Southern, Abstract).

8. Claims 97, 157-160, 163-170, 173-175 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southern et al (Genomics, 1992, 13: 1008-1017) in view of Brigati (U.S. Patent No. 4,777,020, issued 11 October 1988).

Regarding Claims 97, 157-158 and 166-168, Southern et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (Fig. 3, figure legend, line 1).

Southern teaches each array is in one of four quadrants on the surface (Fig. 3). The four-quadrant arrangement is encompassed by the physical separation because a quadrant defines a physical location of the surface. Assignment of an array to a quadrant defines a boundary between quadrants, the boundary being the point of physical separation. While the reference specifically teaches that the arrays are physically separated, Southern does not specifically teach a physical or hydrophobic barrier. However, physical and hydrophobic barriers separating hybridization regions were well known and routinely practiced in the art at the time the instant invention was made as taught by Brigati who teaches that the groove and hydrophobic barriers provide for comparative analysis of hybridization to the same probes to different

samples and/or hybridization of different probes to the same sample (Column 9, line 63-Column 10, line 15).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the physical separation of Brigati to the multiple arrays of Southern. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the benefit of comparative analysis of the multiple arrays to different samples as desired in the art (Brigati, Column 9, line 63-Column 10, line 15).

Regarding Claims 159 and 169, Southern et al disclose the support wherein the microchips are arranged in multiple rows and columns (i.e. two rows and two columns, Fig. 3). And Brigati discloses the support comprising multiple rows and columns (e.g. 30 slide pairs providing 2 rows of 30 columns, Column 7, lines 44-45)

Regarding Claims 160 and 170, Southern et al disclose the support wherein the microchips are positioned for use with a multichannel pipette (Fig. 3). The arrays of Southern are arranged in two rows of two columns. While Southern does not teach use of a multichannel pipette, the courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Southern teaches the structural elements of the claim and therefore, teaches the support of Claims 160 and 170.

Regarding Claims 163 and 173, Southern et al disclose the support wherein the array of microchips comprises more than 256 probes i.e. each of the four microchips has 256 probes. Hence, the support of Claim 97 has more than 256 probes per array as claimed.

Regarding Claims 164 and 174, Southern et al disclose the support wherein the probes are between 4 and 9 bases (Fig. 3).

Regarding Claims 165 and 175, Southern et al disclose the support wherein the probes are synthesized on the support (page 1009, left column). Southern et al do not teach light-directed synthesis. However, the courts have stated that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Because determination of patentability is based on the product and because Southern et al teach the product, the process of making the product as recited in the claim does not define the product over that of Southern.

Conclusion

9. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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